

**The Department of Health and Human Services
Meeting of the
Secretary's Advisory Committee on Human Research Protections (SACHRP)
Tuesday, October 4, 2011 – Wednesday, October 5, 2011
Hubert H. Humphrey Building, Room 800
AGENDA**

Tuesday, October 4, 2011

8:30 am – 8:45 am	Welcome: Opening Remarks Barbara Bierer, M.D. SACHRP Chair
8:45 am – 9:00 am	Opening Remarks, Report of Issues Jerry Menikoff, M.D., J.D., Director, OHRP
9:00 am – 10:00 am	Facilitating IRB Review for Single Patient Treatment Use of Investigational Drugs and Biologics Dominic Cirincione, J.D., M.P.P. Program Analyst FDA Office of Special Health issues
10:00 am – 10:45 am	Subpart A Subcommittee (SAS) and Subcommittee on Harmonization (SOH): <i>Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators</i> Daniel Nelson, M.S., CIP, SAS Co-chair David Borasky, M.P.H., CIP, SAS Co-chair David Forster, J.D., SOH Co-chair Mark Barnes, J.D., SOH Co-chair
10:45 am- 11:00 am	BREAK
11:00 am – 12:30 pm	Discussion
12:30 pm – 1:30 pm	LUNCH
1:30 pm – 3:15 pm	Discussion
3:15 pm – 3:30 pm	BREAK
3:30 pm – 4:45 pm	Discussion
4:45 pm – 5:00 pm	Public Comment
5:00 pm – 5:15 pm	Wrap-up Discussion and Adjourn

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9:15 am- 10:45 am	Discussion of Recommendations to ANPRM
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